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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,481	03/10/2004	John G. Stark	3223.01US02	3292

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EXAMINER

REIMERS, ANNETTE R

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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08/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/797,481

Applicant(s)

STARK, JOHN G.

Examiner

Annette R. Reimers

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-24 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-24 and 28-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-23, 28, 29, 32, 33, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by the Cain (U.S. Patent Number 5,334,205).

Cain discloses a method for immobilizing a patient's sacroiliac joint comprising inserting an immobilization/fusion element into the opening of the sacroiliac joint between the ilium, 56, and the sacrum, 54, through a cannula, e.g. 68, that is placed through an incision formed in the patient, drilling a region at the sacroiliac joint through the cannula, and placing a guide pin, e.g. 70, through the cannula, further including a trocar, e.g. 66, self-tapping screws, e.g. 58, and a drilling guide (see figures 3-5 and column 4, lines 4-48).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Chang et al. (U.S. Patent Publication Number 20020099288)

Cain discloses the claimed method except for the use of real time imaging. Chang et al. discloses the use of real time imaging in order to guide the placement and orientation of an object (see paragraph 0013 and paragraph 0032). It would have been obvious to one skilled in the art at the time the invention was made to incorporate in the method of Cain the use of imaging in view of Chang et al., in order to guide the placement and orientation of the pin.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Bowman et al. (U.S. Patent Number 4,950,270).

Cain discloses the claimed invention except for the screw being associated with or coated with a biologically active agent. Bowman discloses a screw and teaches that the screw is constructed and/or coated with a biocompatible material and teaches the use of biocompatible material to allow for permanent or long term placement in association with cancellous bone and soft tissues and to promote osteointegration (see Column 3, lines 13-17). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Cain with the screw being associated with or coated with a biologically active agent in view of Bowman, in order to allow for permanent or long term emplacement in association with cancellous bone and soft tissues and to promote osteointegration.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205).

Cain discloses the claimed invention except for the immobilization/fusion element being an unthreaded pin. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the immobilization/fusion element without any threads, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an immobilization/fusion element for the joint. In re Dailey and Eilers, 149 USPQ 47 (1966).

Response to Arguments

Applicant's arguments filed April 30, 2207 have been fully considered, but they are not persuasive. Examiner respectfully disagrees with applicant regarding the Cain reference. Although as pointed out by applicant, the screws of the Cain reference are placed across the sacroiliac (SI) joint, the screws are also being placed into the opening of the SI joint between the ilium, 56, and the sacrum, 54 (see figure 5). If applicant means that the immobilization/fusion element is inserted into the SI joint only, then that is what should be claimed. In other words, applicant should claim that the immobilization/fusion element is inserted into the SI joint only or exclusively without passing through or into the ilium and/or the sacrum.

Regarding Cain in view of Cheng et al, examiner is aware that the Cheng et al. does not teach immobilization of the SI joint using real time imaging. However, as stated

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above, Cheng et al. was cited for the use of real time imaging in order to guide the placement and orientation of an object. As previously stated, Cain discloses the claimed method except for the use of real time imaging. Chang et al. discloses the use of real time imaging in order to guide the placement and orientation of an object (see paragraph 0013 and paragraph 0032). It would have been obvious to one skilled in the art at the time the invention was made to incorporate in the method of Cain the use of imaging in view of Chang et al., in order to guide the placement and orientation of the pin. Moreover, it is well known in the art to use real time imaging to guide the placement and orientation of an object.

Regarding Cain in view of Bowman et al., examiner is aware that the Bowman et al. does not teach procedures applied to the SI joint. However, as stated above, Bowman et al. was cited for teaching a screw constructed and/or coated with a biocompatible material to allow for permanent or long term placement in association with cancellous bone and soft tissues and to promote osteointegration. As stated above, Cain discloses the claimed invention except for the screw being associated with or coated with a biologically active agent. Bowman discloses a screw and teaches that the screw is constructed and/or coated with a biocompatible material and teaches the use of biocompatible material to allow for permanent or long term emplacement in association with cancellous bone and soft tissues and to promote osteointegration (see Column 3, lines 13-17). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Cain with the screw being associated with or coated with a biologically active agent, in view of Bowman, in order to allow for

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permanent or long term emplacement in association with cancellous bone and soft tissues and to promote osteointegration. Moreover, the use of bone ingrowth agents is well known in the art.

Examiner also respectfully disagrees with applicant's argument that Cain teaches away from the use of an unthreaded implant. Examiner understands that pulling the joint together is the opposite of distending the joint. However, based on applicant's arguments, examiner does not understand how this is relevant to the use of a threaded or a non-threaded implant, since both a threaded implant and a non-threaded implant are each equally capable of being used to distend a joint. Furthermore, it is noted that the features upon which applicant relies (i.e., arguments regarding distention of the SI joint for immobilization) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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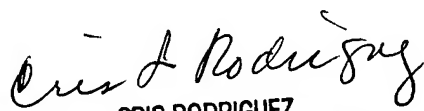
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR



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